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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/937,756	09/25/1997	DAVID C. RUEGER	STK-P06-504	2132

1473 7590 07/24/2008

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PATENT DOCKETING 39/361
1211 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-8704

EXAMINER	
WANG, CHANG YU	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
07/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/937,756	RUEGER ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *97,99 and 105-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *97, 99, and 105-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed 4/18/08 is acknowledged. Claims 1-96, 98, 100-104 are cancelled. Claims 97, 99, and 105-113 are amended. Claims 114-120 are newly added. Claims 97, 99, 105-113 and newly added claims 114-120 are pending in this application and under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. Applicant's arguments filed on 4/18/08 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Withdrawn

5. The rejection of claims 97 and 105-112 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in response to Applicant's amendment to the claims.

Claim Rejections/Objections Maintained

In view of the amendment filed on 4/18/08, the following rejections are maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 97, 99, and 105-120 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of decreasing neuronal death associated with a neuropathy or injury in which neuronal survival is mediated by expression of NCAM or L1 by administering to a subject with a morphogen comprising a dimeric protein having fragments of amino acids 38-139 and 43-139 of SEQ ID NO:5 with homology as recited in claim 97, does not reasonably provide enablement for a method for decreasing neuronal cell death associated with all forms of neuropathy or injury comprising administering a morphogen to a subject afflicted with all forms of neuropathy characterized by undefined altered N-CAM or L1 isoform expression or all forms of chemical or physical injury characterized by undefined altered N-CAM or L1 isoform expression as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

At p. 9-10 of the response, Applicant argues that amended claims are fully enabled because the claims have been amended to recite “neuropathy or injury is characterized by altered NCAM or L1 isoform expression” and the specification provides examples to show the ability of morphogens to enhance neuronal cell survival and also teaches the association between altered NCAM or L1 expression and a number of neuropathies. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, although the specification describes altered NCAM or L1 expression is associated with some forms of neuropathy, the specification fails to teach such

association in a specific manner; in particular, what form of neuropathy or what form of injury is associated with which level of altered NCAM or L1 isoform expression (i.e. an increased or decreased expression of NCAM or L1 isoform). Neither the claims nor the specification defines which level of the NCAM or L1 isoform expression is associated with which form of neuropathy or injury in a specific manner (i.e. increased or decreased expression is associated with the disorder or injury). Since Applicant has not limited the neuropathy or chemical/physical injury, it is not known whether the increased or decreased expression of NCAM or L1 isoform is used to characterize the recited neuropathy or injury. It is also not known what level of the change of the NCAM or L1 isoform expression is associated with the claimed neuropathy or injury and thereby within the limitations of the claims. Since neither the specification nor the prior art teaches what specific form of neuropathy or injury is associated with which level of the altered NCAM or L1 isoform expression in a specific manner, it is unpredictable what form of neuropathy or injury is characterized by increased or decreased NCAM or L1 isoform expression, and thus can be treated by the claimed morphogen. Accordingly, a skilled artisan cannot contemplate what forms of neuropathy or injury can be treated and are within the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, it is unpredictable what diseases or injury have what form of the change of the NCAM or L1 expression and thus can be treated by the claimed method; and the experimentation left to those skilled in the art is extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986). Thus, the skilled artisan

cannot readily make and use the claimed invention as currently claimed without further undue experimentation. Note that

"The 'predictability or lack thereof' in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971)" See MPEP § 2164.03

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

Thus, the rejection of claims 97, 99, and 105-120 under 35 U.S.C. §112, first paragraph, because the specification does not enable the invention commensurate in scope with the claims is maintained.

7. Claims 99, 105-111, and 113-120 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The rejection based on the limitations recited in the original claims is

withdrawn in response to Applicant's amendment to the claims. However, the rejection is maintained in view of Applicant's amendment to claims by reciting new limitation "chemical or physical injury is characterized by altered N-CAM or L1 isoform expression" in independent claims 99 and 113.

At p. 10 of the response, Applicant argues that new limitations recited in independent claims 97, 99, 112 and 113 can be found in the specification on p.16, lines 19-23; p. 70, line 16-p.72, line 4 and p. 76, lines 1-33. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the specification only discloses a neuropathy characterized by altered NCAM or L1 isoform expression on the above described pages but fails to disclose "a chemical/physical injury characterized by altered NCAM or L1 isoform expression in independent claims 99 and 113. The limitation "a chemical or physical injury is characterized by altered NCAM or L1 isoform expression" was not clearly disclosed in the specification and claims as filed, and now changes the scope of the instant disclosure as filed. Such limitation recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Accordingly, in the absence of sufficient recitations of "a chemical or physical injury is characterized by altered NCAM or L1 isoform expression", the original specification does not provide adequate written description to support the limitation as recited in claims 99 and 113. Thus these recitations constitute new matter absent evidence for their support. Applicant is required to cancel the new matter in the reply to

this office action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

Conclusion

8. NO CLAIM IS ALLOWED.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should

applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
July 17, 2008

/Christine J Saoud/
Primary Examiner, Art Unit 1647